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(54) **Apparatus for marking tissue**

Gerät zur Markierung von Gewebe

Appareil de marquage de tissus

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Description

Background of the Invention

[0001] This invention relates to methods and devices for marking and defining particular locations in body tissue, particularly human tissue, and more particularly relates to methods and devices for permanently defining the location and margins of lesions detected in biopsy cavity walls.

[0002] It is desirable and often necessary to perform procedures for detecting, sampling, and testing lesions and other abnormalities in the tissue of humans and other animals, particularly in the diagnosis and treatment of patients with cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of cancer, when a physician establishes by means of known procedures (i.e. palpation, x-ray, MRI, or ultrasound imaging) that suspicious circumstances exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In FNA biopsy, very small needles are used to obtain individual cells or clusters of cells for cytologic examination. The cells may be prepared such as in a Papanicolaou (Pap) smear. In core biopsy, as the term suggests, a core or fragment of tissue is obtained for histologic examination which may be done via a frozen section or paraffin section. The chief difference between FNA and core biopsy is the size of the tissue sample taken. A real time or near real time imaging system having stereoscopic capabilities, such as the stereotactic guidance system described in U.S. Patent No. 5,240,011, is employed to guide the extraction instrument to the lesion. Advantageous methods and devices for performing core biopsies are described in the assignee's U.S. Patent No. 5,526,822.

[0003] Depending upon the procedure being performed, it is sometimes desirable to completely remove suspicious lesions for evaluation, while in other instances it may be desirable to remove only a sample from the lesion. In the former case, a major problem is the ability to define the margins of the lesions at all times during the extraction process. Visibility of the lesion by the imaging system may be hampered because of the distortion created by the extraction process itself as well as associated bleeding in the surrounding tissues. Although the lesion is removed and all fluids are continuously aspirated from the extraction site, it is likely that the process will "cloud" the lesion, thus impairing exact recognition of its margins. This makes it difficult to ensure that the entire lesion will be removed

[0004] Often, the lesion is merely a calcification derived from dead abnormal tissue, which may be cancerous or pre-cancerous, and it is desirable to remove only a sample of the lesion, rather than the entire lesion, to evaluate it. This is because such a lesion actually serves to mark or define the location of adjacent abnormal tissue, so the physician does not wish to remove the entire lesion and thereby lose a critical means for later re-locating the affected tissue. One of the benefits to the patient from core biopsy is that the mass of the tissue taken is relatively small. However, oftentimes, either inadvertently or because the lesion is too small, the entire lesion is removed for evaluation, even though it is desired to remove only a portion. Then, if subsequent analysis indicates the tissue to be malignant (malignant tissue requires removal, days or weeks later, of tissue around the immediate site of the original biopsy), it is difficult for the physician to determine the precise location of the lesion, in order to perform necessary additional procedures on adjacent potentially cancerous tissue. Additionally, even if the lesion is found to be benign, there will be no evidence of its location during future examinations to mark the location of the previously removed calcification so that the affected tissue may be carefully monitored for future reoccurrences.

[0005] Thus, it would be of considerable benefit to be able to permanently mark the location or margins of such a lesion prior to or immediately after removing or sampling same. Marking prior to removal would help to ensure that the entire lesion is excised, if desired. Alternatively, if the lesion were inadvertently removed in its entirety, marking the biopsy site immediately after the procedure would enable re-establishment of its location for future identification.

[0006] A number of procedures and devices for marking and locating particular tissue locations are known in the prior art. For example, location wire guides, such as that described in U.S. Patent No. 5,221,269 to Miller et al, are well known for locating lesions, particularly in the breast. The device described by Miller comprises a tubular introducer needle and an attached wire guide, which has at its distal end a helical coil configuration for locking into position about the targeted lesion. The needle is introduced into the breast and guided to the lesion site by an imaging system of a known type, for example, x-ray, ultrasound, or magnetic resonance imaging (MRI), at which time the helical coil at the distal end is deployed about the lesion. Then, the needle may be removed from the wire guide, which remains in a locked position distally about the lesion for guiding a surgeon down the wire to the lesion site during subsequent surgery. While such a location system is effective, it is obviously intended and designed to be only temporary, and is removed once the surgery or other procedure has been completed.

[0007] Other devices are known for marking external regions of a patient's skin. For example, U.S. Patent No. 5,192,270 to Carswell, Jr. discloses a syringe which dispenses a colorant to give a visual indication on the surface of the skin of the point at which an injection has or

will be given. Similarly, U.S. Patent No. 5,147,307 to Gluck discloses a device which has patterning elements for impressing a temporary mark in a patient's skin, for guiding the location of an injection or the like. It is also known to tape or otherwise adhere a small metallic marker, e.g. a 3 millimeter diameter lead sphere, on the skin of a human breast in order to delineate the location of skin calcifications (see Homer et al, *The Geographic Cluster of Microcalcifications of the Breast,* Surgery, Gynecology, & Obstetrics, December 1985). Obviously, however, none of these approaches are useful for marking and delineating internal tissue abnormalities, such as lesions or tumors.

[0008] Still another approach for marking potential lesions and tumors of the breast is described in U.S. Patent No. 4,080,959. In the described procedure, the skin of the portion of the body to be evaluated, such as the breasts, is coated with a heat sensitive color-responsive chemical, after which that portion of the body is heated with penetrating radiation such as diathermy. Then, the coated body portion is scanned for color changes which would indicate hot spots beneath the skin surface. These so-called hot spots may represent a tumor or lesion, which does not dissipate heat as rapidly because of its relatively poor blood circulation (about 1/20 of the blood flow through normal body tissue). This method, of course, functions as a temporary diagnostic tool, rather than a permanent means for delineating the location of a tumor or lesion.

[0009] A method of identifying and treating abnormal neoplastic tissue or pathogens within the body is described in U.S. Patent No. 4,649,151 to Dougherty et al. In this method, a tumor-selective photosensitizing drug is introduced into a patient's body, where it is cleared from normal tissue faster than it is cleared from abnormal tissue. After the drug has cleared normal tissue but before it has cleared abnormal neoplastic tissue, the abnormal neoplastic tissue may be located by the luminescence of the drug within the abnormal tissue. The fluorescence may be observed with low intensity light, some of which is within the drug's absorbance spectrum, or higher intensity light, a portion of which is not in the drugs absorbance spectrum. Once detected, the tissue may be destroyed by further application of higher intensity light having a frequency within the absorbance spectrum of the drug. Of course, this method also is only a temporary means for marking the abnormal tissue, since eventually the drug will clear from even the abnormal tissue. Additionally, once the abnormal tissue has been destroyed during treatment, the marker is destroyed as well.

[0010] It is also known to employ biocompatible dyes or stains to mark breast lesions. First, a syringe containing the colorant is guided to a detected lesion, using an imaging system. Later, during the extraction procedure, the surgeon harvests a tissue sample from the stained tissue. However, while such staining techniques can be effective, it is difficult to precisely localize the stain. Also, the stains are difficult to detect fluoroscopically and may not always be permanent.

[0011] Additionally, it is known to implant markers directly into a patient's body using invasive surgical techniques. For example, during a coronary artery bypass graft (CABG), which of course constitutes open heart surgery, it is common practice to surgically apply one or more radiopaque rings to the aorta at the site of the graft. This enables a practitioner to later return to the site of the graft by identifying the rings, for evaluative purposes. It is also common practice to mark a surgical site with staples, vascular clips, and the like, for the purpose of future evaluation of the site.

[0012] A technique has been described for the study of pharyngeal swallowing in dogs, which involves permanently implanting steel marker beads in the submucosa of the pharynx (S.S. Kramer et al, *A Permanent Radiopoque Marker Technique for the Study of Pharyngeal Swallowing in Dogs,* Dysphagia, Vol. 1, pp. 163-167, 1987). The article posits that the radiographic study of these marker beads during swallowing, on many occasions over a substantial period of time, provides a better understanding of the pharyngeal phase of degluitition in humans. In the described technique, the beads were deposited using a metal needle cannula having an internal diameter slightly smaller than the beads to be implanted. When suction was applied to the cannula, the bead sat firmly on the tip. Once the ball-tipped cannula was inserted through tissue, the suction was broken, thereby releasing the bead, and the cannula withdrawn.

[0013] Accordingly, what is needed is a method and device for non-surgically implanting potentially permanent markers at the situs of a lesion or other abnormal tissue, for the purpose of defining the margins of a lesion before it is removed and/or to establish its location after it has been removed. The markers should be easy to deploy and easily detected using state of the art imaging techniques. WO9608208 provides such a device. It forms the basis for the preamble of claim 1, appended hereto. US4909250 also discloses a marker implanting device, although the markers are degradeable and are for marking sources of meat for identification after slaughter.

Summary of the Invention

[0014] This invention solves the problems noted above by providing an implantable marking device which is designed to percutaneously deliver permanent markers to desired tissue locations within a patient's body, even if the desired locations are laterally disposed relative to the distal end of the delivery device, as is the case for conduit or cavity walls. The device is an introducer as defined in claim 1, appended hereto. The device allows the physician to accurately position and deploy a radiographic clip at the site of a biopsy. This provides several advantages to the physician in diagnosis

and management of tissue abnormalities, such as a means of localization of a tissue abnormality for follow-up surgical treatment, and a means of tissue abnormality site identification for purposes of ongoing diagnostic follow-up. It may also prevent inadvertent repeat biopsy of a lesion if the patient were to move or if adequate records did not follow the patient. The inventive system also represents a less traumatic means for tissue marking and a reduced procedural duration relative to the standard open surgical method.

[0015] In a first embodiment of the invention, a flexible tissue marker introducer is employed. The flexible tissue marker introducer incorporates a flexible tube that allows the physician to access and deliver the tissue marker through a cassette housing on the biopsy probe. Additionally, the introducer employs a distal tip ramp feature which enables the tissue marker to be advanced laterally out of a laterally facing sample notch at a distal end of the biopsy probe, so that the tissue marker can be fixed to the side wall of the tissue cavity. One important inventive feature is the inclusion of an orientation mark on the hub of the introducer to allow the physician to obtain the desired placement position at the biopsy site.

[0016] In a second embodiment of the invention, a rigid introducer is utilized rather than a flexible introducer, so that the biopsy power driver and probe is not necessary to provide a rigid fixed position access channel for the marker delivery system. This embodiment is particularly useful when the biopsy power driver and probe being used is too small to accommodate the aforementioned flexible introducer, and an alternate access and delivery means is required.

[0017] The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

Brief Description of the Drawing

[0018]

Fig. 1 is a perspective view of a first embodiment of the invention, illustrating an arrangement for delivering and deploying a tissue marker through a flexible introducer, utilizing a motor-driven biopsy probe of known construction as an access conduit;

Fig. 2 is a perspective view similar to Fig. 1, wherein the driver portion of the motor-driven biopsy probe has been deleted in order to better isolate the flexible introducer and tissue marker applier;

Fig. 3 is a side elevational view of the flexible introducer and tissue marker applier illustrated in Figs. 1 and 2;

Fig. 4 is a cross-sectional view of the distal end portion 4-4 of the flexible introducer illustrated in Fig. 3;

Fig. 5 is a perspective view of a second embodiment of the present invention, illustrating an arrangement for delivering and deploying a tissue marker through a rigid introducer;

Fig. 6 is a cross-sectional view of a one-piece marking device constructed in accordance with the principles of the present invention;

Fig. 7 is a cross-sectional view similar to Fig. 6, illustrating the one-piece marking device as the marker thereof is being pulled back against the forming die for partially closing the marker; and

Fig. 8 is a cross-sectional view similar to Fig. 7, illustrating the marker as it is separated from the remainder of the marking device and deployed to mark a desired tissue site.

Detailed Description of the Invention

[0019] Referring now more particularly to Figs. 1-4, a first embodiment of an introducer 10 (best seen in Fig. 3) for delivering tissue markers 12 (Fig. 4) to a wall 14 of a biopsy cavity 16 is illustrated. Tissue markers 12 are preferably comprised of a nonmagnetic, radiographic material, and are preferably constructed in the form of a clip, or surgical staple, to facilitate attachment to the tissue they are intended to identify and to provide an easily recognized shape which would not be mistaken for another lesion. In the preferred embodiment, the maximum width of a tissue marker 12 is within a range of approximately 0.762 to 1.27mm (.030 inches -.050 inches), and preferably about .039 inches (1 mm). To place the marker 12 at a desired tissue location, a biopsy power driver and probe 18 is preferably used, such as the MAMMOTOME® power driver and probe manufactured and sold by Biopsys Medical, Inc., of Irvine, California, the assignee of the present application. As described, for example, in U.S. Patent No. 5,526,822, the biopsy power driver and probe 18 comprises a driver housing 20, a hollow outer piercing needle 22 having a distal piercing end 24, and a tissue cassette housing 26. The hollow outer piercing needle 22 includes a laterally facing tissue receiving port 28 near its distal end. The biopsy power driver and probe 18 is operated to obtain a tissue sample by first moving the distal piercing end 24 of the needle 22 into position to pierce the lesion or selected tissue which is to be sampled, using a known imaging device, such as a stereotactic imaging unit. Then, a vacuum may be drawn through a vacuum port 30 (Fig. 1) of the tissue cassette housing 26, and through the hollow needle 22 to create a negative pressure condition at the tissue receiving port 28, thereby drawing tissue into the port, where it is severed by an inner cutting cannula to capture a tissue sample. The

tissue that is captured within the inner cutting cannula is transported proximally in an intact fashion by retracting the cutting cannula (not shown) rearwardly, preferably to a slot 32 (Fig. 2) in the tissue cassette housing 26. A plurality of tissue samples, from different orientations in the vicinity of the tissue receiving port 28, may be obtained without withdrawing the needle 22.

[0020] Once the desired tissue samples have been captured, thereby creating the biopsy cavity 16, it is often desirable to accurately position and deploy a permanent marker at the site of the biopsy. This provides several advantages to the physician in diagnosis and management of tissue abnormalities. For example, suitable permanent marking of the biopsy site provides a means for relocalizing the area of a tissue abnormality for follow-up surgical treatment, in the event the biopsy pathological results are positive. It also provides a means of tissue abnormality site identification for the purpose of ongoing diagnostic follow-up. To implant a marker in the cavity walls 14, however, requires a marker delivery system which permits accurate lateral discharge of the marker.

[0021] The present invention is particularly advantageous in that it utilizes the lumen of the hollow outer piercing needle 22 as the marker delivery conduit. Thus, subsequent to the biopsy procedure, while the probe 34 (Fig. 2) is still inserted within the patient's body at the biopsy site, it may be utilized as a fixed position, rigid, annular conduit for delivery and deployment of the tissue marker 12. The fact that the probe 34 never leaves the biopsy site ensures accurate delivery of the marker to the cavity 16, while also providing a less traumatic and quicker tissue marking process than the standard open surgical methods.

[0022] With particular reference now to Fig. 3, the flexible introducer 10 of the present invention is illustrated. The introducer 10 comprises a flexible tube 36 having an opening 38 adjacent to its distal end and a hub 40 at its proximal end. As illustrated in Fig. 4, a plug 42 is disposed at the distal end of the flexible tube 36, which plug includes an angled, sloping ramp 44 on a proximal end face thereof. The flexible tube 36 of the flexible introducer 10 is adapted to receive a flexible tube or deployment shaft 46 of a disposable tissue marker applier 48. The applier 48 comprises a squeeze handle 50 on its proximal end, which has a ring 52 to which is attached a pull wire 54. The pull wire 54 extends through the lumen of the deployment shaft 46, and is attached at its distal end to the marker 12 (Fig. 4).

[0023] To deploy a marker 12 into the cavity wall 14, the flexible tube 36 of the introducer 10 is inserted into the hollow needle 22 of the probe 34 through the tissue cassette housing 26, until the hub 40 abuts the tissue cassette housing 26, as illustrated in Figs. 1 and 2. Once fully inserted, the hub 40 is rotated by the physician until an indexing mark or notch 56 (Fig. 3) is properly oriented, thereby ensuring that the introducer 10 is circumferentially aligned within the probe 34.

[0024] After the flexible tube 36 of the flexible introducer 10 has been inserted into the probe 34 and properly oriented, in the manner described above, the tissue marker applier 48 may be advanced into the lumen of the introducer 10, as illustrated in Figs. 1 and 2, so that the distal end thereof exits from the notch 38 and tissue receiving port 28, extending into the cavity 16 (alternatively, the applier 48 may be first inserted into the introducer, and then the introducer may be inserted into the probe 34, if desired). An important aspect of the invention is the use of the ramp 44 to direct the flexible deployment shaft 46 radially outwardly from the notch 38 so that the marker 12 disposed at the distal end of the shaft 46 may be laterally transported to the cavity wall 14 for placement. Once the marker 12 is disposed at a desired marking location, the squeeze handle 50 is squeezed by the physician so that the pull wire 54 is retracted by the squeezing motion sufficiently to break the pull wire, thus releasing the marker 12 for implantation into the target tissue 14.

[0025] Once the marker has been implanted, the flexible deployment shaft 46 may be withdrawn from the introducer 10 and discarded, while a new applier 48 is inserted into the introducer to implant a second marker. As many markers as desired may be implanted, following which the hub 40 may be counter-rotated 90-270 degrees and the entire probe 34 withdrawn from the patient. If it is desired to mark various locations about the cavity wall 14, the probe needle 22 may be rotated between marker implantations to change the orientation of the tissue receiving port 28, using the thumbwheel 58. Additionally, the axial position of the port 28 may be adjusted, if desired.

[0026] Referring now to Fig. 5, a second embodiment of the inventive introducer mechanism is illustrated. In this embodiment, like elements to those of the first embodiment are designated by like reference numerals, followed by the letter a.

[0027] The significant difference between the first embodiment, illustrated in Figs. 1-4, and the embodiment of Fig. 5, is that the introducer 10a is rigid, rather than flexible. The flexible introducer 10 of the first embodiment is adapted for use with a biopsy power driver and probe 18, which functions as the access mechanism. Therefore, the flexible characteristic of the tube 36 is necessary in order to facilitate threading of the tube 36 through the lumen of the needle 22, via the tissue cassette housing 26. This embodiment works very well in connection with larger sized probes, such as 11 gauge MAMMOTOME probes manufactured by Biopsys Medical, Inc., the present assignee, for example. However, the flexible tube 36 is too large to be threaded through smaller probes, such as the 14 gauge MAMMOTOME probe manufactured by the present assignee. Therefore, the second embodiment has been developed to provide a stand alone access device for introducing the tissue marker applier 48a.

[0028] The rigid introducer 10a illustrated in Fig. 5

comprises a rigid tube 36a having a piercing distal end 60, a distal laterally facing opening 38a, and a ramp 62. Since, in this embodiment, the introducer is not delivered through another access device, but rather is itself an access device, it is preferably loaded onto an introducer needle mount 64, so that the shaft 36a is disposed in a shaft channel 66 of the mount 64, and held in position by means of cover portion 68. The biopsy probe and driver 18 are removed from the imaging system (not shown), typically a stereotactic table available from Fischer Imaging, Inc. or from Lorad, Inc. The probe guide holder (not shown) is replaced by the loaded introducer needle mount 64. The introducer is then advanced to the desired tissue sampling site, following which the tissue marker applier is inserted through the introducer cannula to an appropriate depth mark to allow the distal tip clip to extend over the ramp 62 and to extend laterally sufficiently far to pierce tissue. The handle 50a is then squeezed in the manner discussed supra to deploy the distal tip clip 12. Then, the disposable applier is removed.

[0029] A particularly advantageous embodiment of the present invention is the employment of a one-piece marking element 70 (Figs. 6-8), comprising a marker 12b and a marker closing ribbon or pull wire 54b which are comprised of a single piece of wire. In this particular marker embodiment, the single piece marking element 70 is preferably fabricated of a single piece of sheet material, ideally using a photochemical etching process to eliminate any fabrication and thermal stresses from being introduced into the part. The single-piece element is fabricated such that a weak spot or failure point 72 (Figs. 6-7) is disposed at a location on the marking element which will break at a predetermined load after the legs 73, 74 of the marker have closed down and gripped the tissue to which the marker 12b is to be attached. Thus, as illustrated in Figs. 6-8, a forming die 75 is provided which is disposed proximally of the marker portion 12b of the single-piece marking element 70. The failure point 72 is disposed between the forming die 75 and the marker 12b, at the distal end of the pull wire 54b. To deploy the marker 12b into the target tissue, a pulling force is applied proximally to the pull wire 54b, in the direction shown by arrow 76. This pulling force may be applied, for example, by a squeeze handle 50 like that shown in Figs. 1-3 and 5, or by some other means. This proximal pulling force causes the marker portion 12b to travel proximally to a point where it impacts the distal end of the forming die 75, as illustrated in Fig. 7. Continued proximal pulling forces on the pull wire 54b results in closure forces being applied against the legs 73, 74 of the marker portion 12b. Ultimately, as illustrated in Fig. 8, continued application of a proximal pulling force on the pull wire 54b will result in breakage of the pull wire 54b at the failure point 72, so that the marker 12b becomes separated therefrom, with the legs 73, 74 of the marker being closed upon the tissue desired to be marked.

[0030] While the inventive marking element may be round in cross-section, in its preferred embodiment, the marking element 70 is fabricated of rectangular stock, which has been clamped at each end and twisted along its length. The inventors have found that, absent the twisting step, the sharp edges of the rectangular stock tend to snag against the sides of the tube 46 (Fig. 3) as it is being pulled therethrough. Twisting, on the other hand, has been found to soften the edges of the stock sufficiently to ease passage of the pull wire 54b through the tube.

[0031] While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

Claims

1. An introducer (10) for remotely delivering a marker to a particular tissue area within a body to identify said particular tissue area for a later diagnostic or therapeutic procedure, comprising:

   a marker applier comprising a tube or shaft (36) for remotely delivering a marker from outside the body to the particular tissue area, the marker applier comprising a distal lateral opening (38), **characterised in that** the applier comprises an angled ramp (62) disposed adjacent to the distal lateral opening (38), said ramp (62) functioning to provide lateral deployment of said marker from the marker applier.

2. The introducer (10) of claim 1, wherein the marker applier comprises a deployment shaft (46) insertable through an introducer tube (36) for transporting a marker to said particular tissue area.

3. The introducer (10) according to any one of the preceding claims, wherein a portion of the marker applier is capable of being indexed to provide a desired circumferential orientation of the ramp (62).

4. The introducer (10) according to any one of the preceding claims, wherein the marker applier is flexible.

5. The introducer (10) according to any one of the preceding claims, comprising an introducer tube (36) which is flexible.

6. The introducer (10) according to any one of the preceding claims, comprising a deployment shaft (46) having a lumen, a distal end and a proximal end.

7. The introducer (10) according to any one of the pre-

ceding claims, comprising a rigid annular conduit having a distal opening, said rigid annular conduit being adapted for entry into said body using an aided visualization device, wherein the distal opening (38) of the conduit is able to be disposed adjacent to said particular tissue area, an introducer tube (36) being flexible and insertable into said rigid annular conduit such that the distal end of the introducer tube (36) exits said rigid annular conduit through the distal opening (38) thereof, thereby transporting said marker element (12) to said particular tissue area.

8. The introducer (10) of claim 7, wherein said rigid annular conduit comprises a biopsy power driver and probe.

9. The introducer (10) according to any one of the preceding claims, wherein a portion of the distal end of the applier is adapted for piercing and entering said body, such that the distal lateral opening (38) thereof can be disposed adjacent to said particular tissue area.

10. The introducer (10) according to any one of the preceding claims, wherein the marker applier is adapted to deliver a marker element (12) having a width of less than 2.54mm (0.1 inches).

11. The introducer (10) of claim 10, wherein said marker applier is adapted to deliver a marker element having a width within a range of 0.762 to 1.27mm (0.030-0.050 inches)

12. The introducer of any one of the preceding claims, comprising an orientation mark on a hub of the device to allow a physician to obtain a desired orientation for the placement position at the biopsy site.

Patentansprüche

1. Einführungsvorrichtung (10) zur Fernabgabe eines Markers an einen speziellen Gewebebereich innerhalb eines Körpers, um den speziellen Gewebebereich für einen späteren diagnostischen oder therapeutisches Eingriff zu identifizieren, umfassend:

   ein Markerauftragungsmittel umfassend eine Röhre oder einen Schaft (36) zum Fernabgeben eines Markers von außerhalb des Körpers an den speziellen Gewebebereich, wobei das Markerauftragungsmittel eine distale seitliche Öffnung (38) umfasst, **dadurch gekennzeichnet, dass** das Auftragungsmittel eine winkelige schiefe Ebene (62) umfasst, die benachbart der distalen lateralen Öffnung (38) angeordnet ist, wobei die schiefe Ebene (62) so funktioniert, dass ein seitliches Verteilen des Markers von dem Markerauftragungsmittel bereitgestellt wird.

2. Einführungsvorrichtung (10) nach Anspruch 1, wobei das Markerauftragungsmittel einen Verteilschaft (46) umfasst, der durch eine Einführungsröhre (36) einführbar ist, um einen Marker zu dem speziellen Gewebebereich zu transportieren.

3. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche, wobei ein Teil des Markerauftragungsmittels in der Lage ist, weitergeschaltet zu werden, um eine erwünschte Umfangsausrichtung der schiefen Ebene (62) bereitzustellen.

4. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche, wobei das Markerauftragungsmittel flexibel ist.

5. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche, umfassend ein flexibles Einführungsrohr (36).

6. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche, umfassend einen Verteilschaft (46) mit einem Hohlraum, einem distalen Ende und einem proximalen Ende.

7. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche umfassend einen steifen ringförmigen Kanal mit einer distalen Öffnung, wobei der steife ringförmige Kanal angepasst ist für den Eintritt in den Körper unter Verwendung einer halbautomatischen Visualisierungsvorrichtung, wobei die distale Öffnung (38) des Kanals in der Lage ist, benachbart dem speziellen Gewebebereich angeordnet zu werden, eine Einführungsröhre (36) flexibel ist und in den steifen ringförmigen Kanal eingeführt werden kann, so dass das distale Ende der Einführungsröhre (36) aus dem steifen ringförmigen Kanal durch dessen distale Öffnung (38) austritt, wodurch das Markerelement (12) zu dem speziellen Gewebebereich transportiert wird.

8. Einführungsvorrichtung (10) nach Anspruch 7, wobei der steife ringförmige Kanal einen Biopsiemotorantrieb und eine Sonde umfasst.

9. Einführungsvorrichtung (10) nach einem der vorangehenden Ansprüche, wobei ein Teil des distalen Endes des Auftragungsmittels angepasst ist, um den Körper zu durchstechen und darin einzudringen, so dass die distale seitliche Öffnung (38) davon benachbart zu dem speziellen Gewebebereich angeordnet sein kann.

10. Einführungsvorrichtung (10) nach einem der voran-

gehenden Ansprüche, wobei das Markerauftragungsmittel angepasst ist um ein Markerelement (12) abzugeben, das eine Weite von weniger als 2,54 mm (0,1 Zoll) aufweist.

11. Einführungsvorrichtung (10) nach Anspruch 10, wobei das Markerauftragungsmittel angepasst ist, um ein Markerelement mit einer Weite innerhalb eines Bereiches von 0,762 bis 1,27 mm (0,030-0,050 Zoll) abzugeben.

12. Einführungsvorrichtung nach einem der vorangehenden Ansprüche, umfassend eine Ausrichtungsmarkierung auf einem Sitz der Vorrichtung, um dem Arzt zu erlauben, eine erwünschte Ausrichtung für die Platzierungsposition an der Biopsiestelle zu erhalten.

Revendications

1. Dispositif d'introduction (10) afin de délivrer à distance un marqueur à une zone de tissu particulière à l'intérieur d'un corps pour identifier une zone de tissu particulière pour une procédure de diagnostic ou thérapeutique ultérieure, comprenant :

   un dispositif d'application de marqueur comprenant un tube ou une tige (36) pour délivrér à distance un marqueur à partir de l'extérieur du corps vers une zone de tissu particulière, le dispositif d'application de marqueur comprenant une ouverture latérale distale (38), **caractérisé en ce que** le dispositif d'application comprend une rampe inclinée (62) disposée adjacente à l'ouverture latérale distale (38), ladite rampe (62) fonctionnant pour fournir un déploiement latéral dudit marqueur à partir du dispositif d'application de marqueur.

2. Dispositif d'introduction (10) selon la revendication 1, dans lequel le dispositif d'application de marqueur comprend une tige de déploiement (46) qui peut être insérée à travers un tube du dispositif d'introduction (36) pour transporter un marqueur vers ladite zone de tissu particulière.

3. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, dans lequel une partie du dispositif d'application de marqueur est capable d'être indexée pour fournir une orientation circonférentielle désirée de la rampe (62).

4. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, dans lequel le dispositif d'application de marqueur est souple.

5. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, comprenant un tube de dispositif d'introduction qui est souple.

6. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, comprenant une tige de déploiement (46) qui possède une lumière, une extrémité distale et une extrémité proximale.

7. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, comprenant un conduit annulaire rigide possédant une ouverture distale, ledit conduit annulaire rigide étant conçu pour pénétrer dans ledit corps à l'aide d'un dispositif de visualisation assistée, dans lequel l'ouverture distale (38) du conduit peut être disposée adjacente à ladite zone de tissu particulière, un tube de dispositif d'introduction (36) étant souple et pouvant être inséré dans ledit conduit annulaire rigide de telle sorte que l'extrémité distale du tube de dispositif d'introduction (36) sorte dudit conduit annulaire rigide à travers l'ouverture distale (38) de celui-ci, en transportant de ce fait ledit élément de marqueur (12) vers ledit secteur de tissu particulier.

8. Dispositif d'introduction (10) selon la revendication 7, dans lequel ledit conduit annulaire rigide comprend un dispositif de commande de biopsie et une sonde.

9. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, dans lequel une partie de l'extrémité distale du dispositif d'application est conçue pour perforer, et pénétrer dans, ledit corps, de telle sorte que l'ouverture latérale distale (38) de celui-ci puisse être disposée adjacente audit secteur de tissu particulier.

10. Dispositif d'introduction (10) selon l'une quelconque des revendications précédentes, dans lequel le dispositif d'application de marqueur est conçu pour délivrer un élément de marqueur (12) dont la largeur est inférieure à 2.54 mm (0.1 pouce).

11. Dispositif d'introduction (10) selon la revendication 10, dans lequel ledit dispositif d'application de marqueur est conçu pour délivrer un élément de marqueur qui possède une largeur située dans une plage comprise entre 0.762 mm et 1.27 mm (0.030 pouce - 0.050 pouce)

12. Dispositif d'introduction selon l'une quelconque des revendications précédentes, comprenant une marque d'orientation située sur un moyeu du dispositif pour permettre à un médecin d'obtenir une orientation désirée de la position du placement au niveau du site où est effectuée la biopsie.

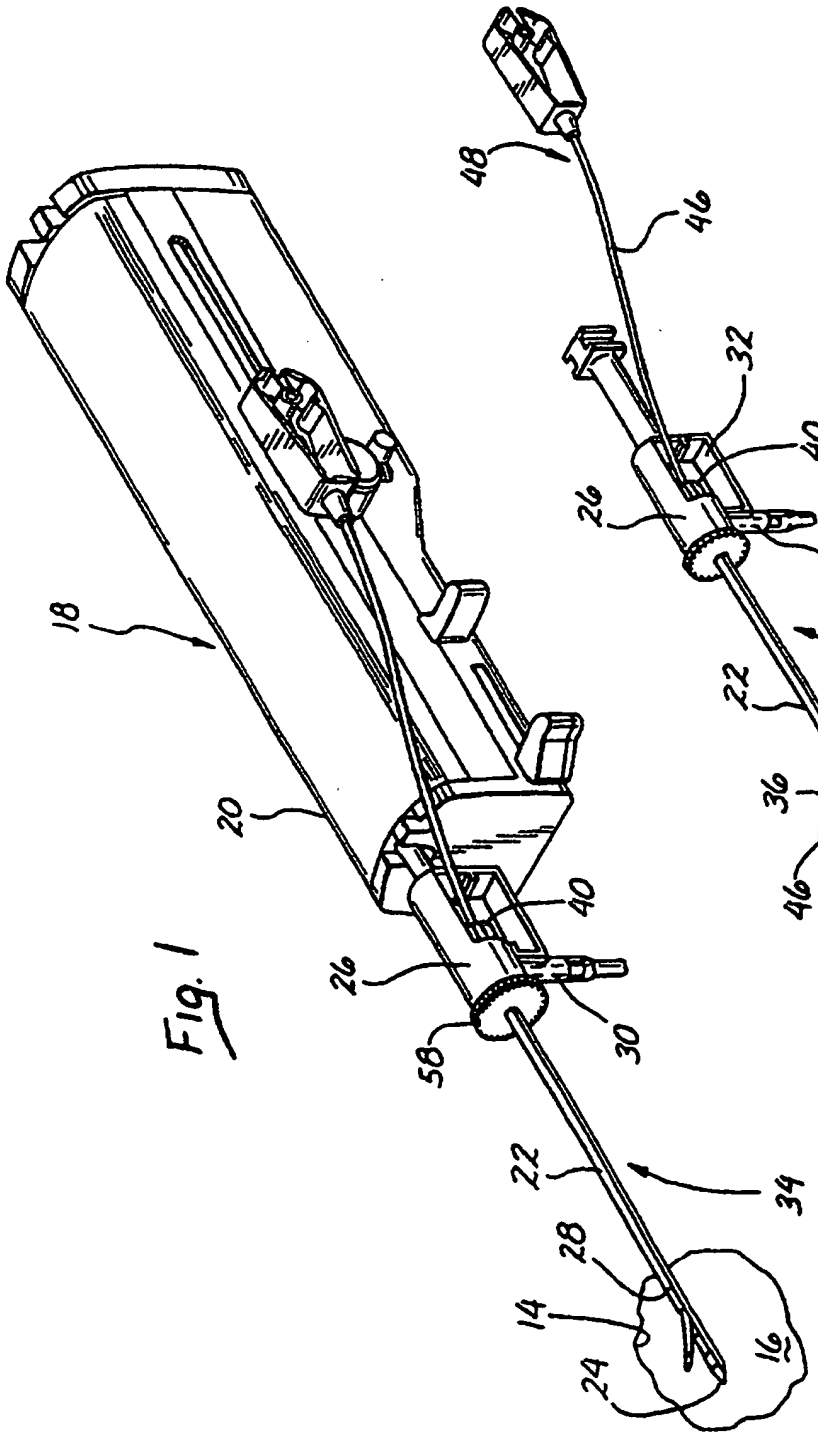

Fig. 1

Fig. 2

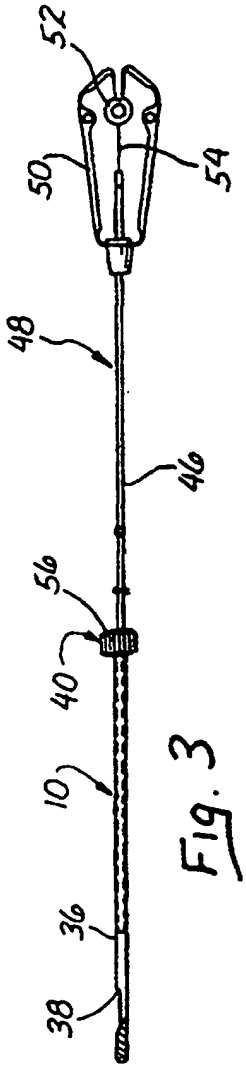

Fig. 3

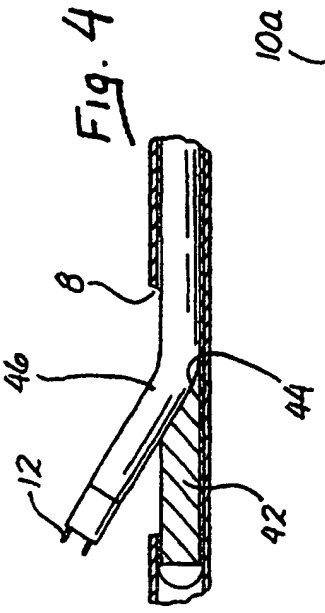

Fig. 4

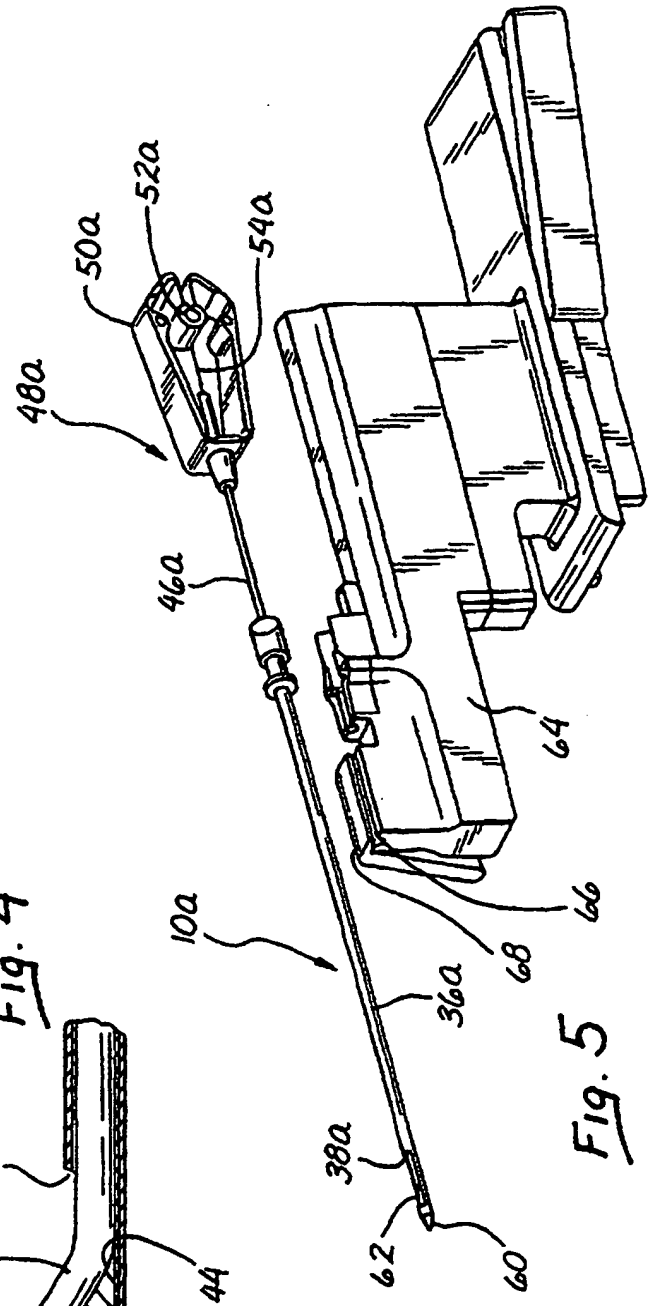

Fig. 5

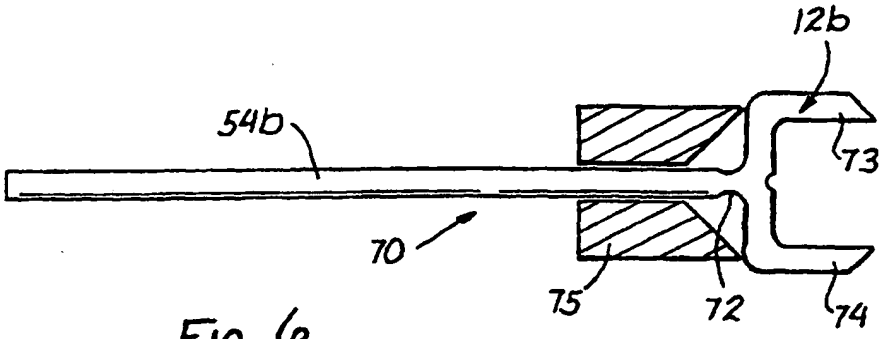

Fig. 6

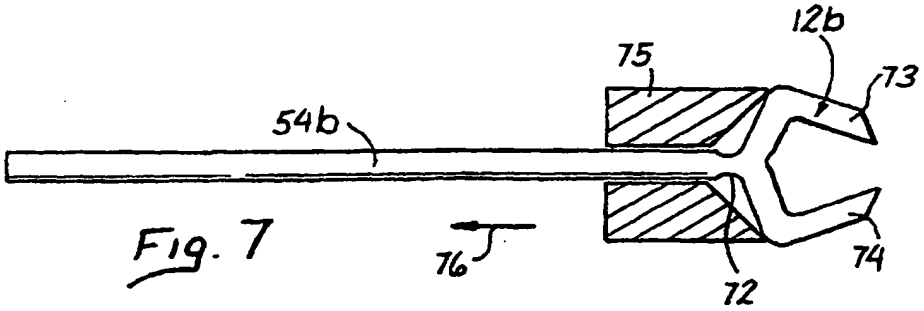

Fig. 7

Fig. 8